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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/812,238

03/29/2004

Kishore K. Wary

D6563

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7590

05/18/2005

Dr. Benjamin Adler
ADLER & ASSOCIATES
8011 Candle Lane
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EXAMINER

HADDAD, MAHER M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/812,238

Applicant(s)

WARY ET AL.

Examiner

Maher M. Haddad

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☐ Claim(s) _____ is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Notice to comply with requirements for sequences.

DETAILED ACTION

1. The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Maher Haddad, Art Unit 1644, Technology Center 1600.

2. Applicant's election of Group II claims 10-11 and 16-17 and 27-33 of the embodiment of the method of inhibiting cell-cell interaction or treating a patient having a pathological condition resulting from integrin-mediated cell-cell interaction or inhibiting angiogenesis and the formation of capillaries in a patient, the method comprising the step of blocking the binding of integrins to VCIP by an antibody directed against a peptide derived from VCIP, an antibody directed against a peptide derived from VCIP and a diagnostic kit comprising the same antibody, filed 3/10/05, is acknowledged. Upon reconsideration, however, the previous restriction requirement is vacated. A new restriction follows. The Examiner apologizes for any inconvenience or delay.

Sequence Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The specification contains the amino acid sequence at pages 18, line 10, 36, line 25, and claims 10, 16 and 18, which are not present in sequence listing.

Applicant is reminded of the sequence rules which require a submission for all sequences of more than 9 nucleotides or 3 amino acids (see 37 CFR 1.821-1.825) and is also requested to carefully review the submitted specification for any and all sequences which require compliance with the rules.

4. The specification is objected to under 37 CFR 1.821(d) for failing to provide a sequence identifier for each individual sequence. For Example Table 1, on page 34, has described amino acid sequences of RGD containing peptides that each must have a sequence identifier. Correction is required.

5. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

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- I. Claims 1-7 and 37-41, drawn to a method of enhancing cell-cell interaction comprising the step of expressing a vascular endothelial growth factor and type I collagen inducible protein (VCIP) having the sequence of SEQ ID NO: 13, classified in Class 514, subclass 44.
- II. Claims 10-11, 16-17 and 32-33, drawn to a method of inhibiting cell-cell interaction, a method of treating a patient having a pathological condition and a method of inhibiting angiogenesis and the formation of capillaries in patient with antibody directed against a peptide comprises CRGDD sequence; classified in Class 424, subclass 130.1.
- III. Claims 12-13, 18-19 and 34-35, drawn to a method of inhibiting cell-cell interaction, a method of treating a patient having a pathological condition and a method of inhibiting angiogenesis and the formation of capillaries in patient with a peptide comprises RGD sequence; classified in Class 424, subclass 185.1 and Class 514, subclass 2.
- IV. Claims 22-24, drawn to a peptide derived from vascular endothelial growth factor and type I collagen inducible protein (VCIP); classified in Class 530, subclasses 326-330.
- V. Claims 25-26, drawn to a vector comprising nucleotide sequence that encodes a peptide comprising a CRGDDD sequence, classified in Class 435, subclass 320.1.
- VI. Claims 27-31, drawn to an antibody directed against a peptide comprising a CRGDDD sequence and a kit thereof, classified in Class 530, subclass 387.9 and Class 435, subclass 975.
- VII. Claim 36, drawn a method of inhibiting angiogenesis and the formation of capillaries in a patient in need of such treatment with antisense oligonucleotides against the transcript encoding vascular endothelial growth factor and type I collagen inducible protein, classified in Class 514, subclass 44.

Claims 8-9 and 14-15 and 20-21 link inventions of Groups II and III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 8-9 and 14-15 and 20-21. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory

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and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Groups IV-VI are different products. Peptides, antibodies to the peptides and vectors differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

7. Groups I-III and VII are different methods. Various methods of inhibiting and a method of enhancing differ with respect to ingredients (peptide, antibodies or nucleic acid), method steps, and endpoints (inhibiting vs enhancing); therefore, each method is patentably distinct.

8. Groups I/V, II/VI and III/IV are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group VI can be used for affinity purification, in addition to the methods of inhibiting recited. The peptides of Group IV can be used for affinity purification, in addition to the methods of inhibiting recited. The vector of Group V can be used for gene amplification, in addition to the methods of inhibiting recited.

9. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

10. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be

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restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

- A. If any one of Groups I-III is elected, applicant is required to elect a single specific cell-cell interaction contributes to a biological process such as those recited in claims 7, 14 and 20. Further, if either Group II-II is elected, applicant is required to elect a single specific pathological condition such as those recited in claim 21. Furthermore, if Group III is elected, applicant is required to elect a single specific SEQ ID NO such as those recited in claims 13 and 19. These pathological conditions and biological processes are distinct species because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. The peptide sequences are distinct species because their structures are different which, in turn, address different therapeutic endpoints.
- B. If any one of Groups IV or VI is elected, applicant is required to elect a single specific peptide such as SEQ ID NO: 20 or SEQ ID NO: 32. These peptides are distinct species because their structures are different which, in turn, address different therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

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12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

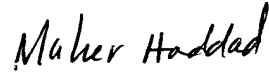
12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 5, 2005


Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: The specification and claims contain sequences which ^{are} not present in the sequence listing.

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE